

**REMARKS**

Claims 1-5, 8, 9, 11, 12 and 14-25 are pending in the above-identified application. Claim 1 has been amended to recite specific amounts of components (a) and (b). Support for the amendment of claim 1 may be found in the previous claim sets. Accordingly, claims 6 and 7 have been cancelled herein. Claim 22 has been amended to correct a typographical error. No new matter has been added by way of the present claim amendments.

***Removal of Issue under 35 USC §112***

Claims 11 and 12 stand rejected under 35 USC §112, second paragraph, there is insufficient antecedent basis for the phrase "Composition according to claim 10". Claims 11 and 12 have been amended to depend upon claim 1. Thus, the basis for this rejection has been removed. Applicant respectfully requests withdrawal of the outstanding rejection.

***Present Invention and Its Advantages***

The present invention, as recited in the present claims, is directed to a composition formulated for oral administration, which includes at least the combination of at least one marrow oil and at least one borage oil, in specific amounts. The composition of the present invention may additionally contain a nettle extract and a soybean extract. *The composition of the present invention unexpectedly and advantageously may be used to treat conditions, such as alopecia, by significantly increasing the anagenic/telogenic ratio.* This is evidenced by the comparative test results described in the present specification and summarized in the Annex 1 (previously submitted on April 23, 2007). Following the protocol described at pages 11-15 of

the present specification, volunteers were administered formulations containing different components as summarized at page 12 of the present specification. As shown in Annex 1, and as summarized in Table 1 at page 13 of the specification, Groups 5-8 (administered combinations of active components) exhibited significantly, advantageously enhanced anagenic/telogenic ratios over Groups 1-4 which were each administered the active components separately. This constitutes significant evidence of unexpected, advantageous properties exhibited by the compositions of the present invention.

*Issues under 35 USC §102(b)*

Claims 1-3, 5, 13 and 15 have been rejected under 35 USC §102(b) as being unpatentable over Deckers '337 (US 2002/0106337).

Claim 1 has been amended to specify the amounts of component (a) marrow oil and component (b) borage oil, as previously recited in claims 6 and 7. Claims 6 and 7 are not subject to the outstanding rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Deckers '337 does not teach or suggest a composition or a method having the specific amounts of marrow oil and borage oil as is presently recited in the claims. Therefore, Deckers '337 cannot properly anticipate the presently claimed invention. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

***Issues Under 35 USC §103(a)***

Claims 1-3, 5-7, 9, 13, 15, 20 and 21 have been rejected under 35 USC §103(a) as being unpatentable over Deckers '337.

Claims 1-22 have been rejected under 35 USC §103(a) as being unpatentable over Deckers '645 (USP 6,146,645).

Claims 1-19 have been rejected under 35 USC §103(a) as being unpatentable over Deckers '645, Duranton '421 (USP 6,465,421), Francis '748 (USP 5,695,748), and Segelman '893 (USP 6,017,893). These rejections are traversed based on the following reasons.

**Deckers '337**

Claim 1 has been amended to specify the amounts of component (a) marrow oil and component (b) borage oil, as previously recited in claims 6 and 7. Claims 6 and 7 are not subject to the outstanding rejection. Therefore, the amendment of claim 1 overcomes the outstanding rejection. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

**Deckers '645**

Deckers '645 discloses a variety of emulsion formulations formed from oil that may be obtained from plants as described at column 7, lines 26-49. Deckers '645 further discloses these formulations may be prepared in the form of a food product as noted at column 3, lines 35-41.

Deckers '645 fails to disclose or suggest anywhere the use of a borage oil as required in all of the composition of the present invention. Since Deckers '645 does not at all disclose the use of a borage oil, it therefore cannot teach the specific amount of the borage oil, as is now required by claim 1. Thus, Deckers '645 fails to satisfy the minimum basic requirements for

alleging *prima facie* obviousness. *In re Vaeck* 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143, Rev. 5, August 2006, p. 2100-126.

In addition, Deckers '645 fails to recognize the unexpected, advantageous properties achieved by the present invention as evidenced by the comparative test results discussed above. Consequently, significant patentable distinctions exist between the present invention and Deckers '645 such that this basis for the above rejection should be withdrawn. In addition, even assuming that *prima facie* obviousness has been properly alleged, such obviousness has been rebutted by the comparative test results discussed above. Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

Deckers '645, Duranton '421, Francis '748, and Segelman '893

All of Duranton '421, Francis '748 and Segelman '893 fail to disclose or suggest the use of marrow oil in a composition, as recited in present claim 1 and required by all of the presently pending claims. Moreover, the cited prior art references do not disclose the specific amount of marrow oil as is now required in claim 1. Thus, the outstanding rejection fails to support an allegation of obviousness under 35 USC §103(a), since the applicable cited references fail to disclose all of the elements recited in the present claims. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Consequently, it is requested that the above-noted rejection be withdrawn.

It is further submitted that, in addition to the above, there fails to be any reasonable suggestion or motivation for one skilled in the art to combine selected components from Deckers '645 with any of the Duranton '421, Francis '748 and Segelman '893 references .

Deckers '645 fails to mention the presence of borage oil. Further, all of these references fail to provide any reasonable suggestion whatsoever regarding the unexpected, advantageous properties evidenced by the comparative test results summarized in Annex 1 and in the present specification, as discussed above. Consequently, even if a *prima facie* case of obviousness has been properly alleged, such obviousness has been rebutted by the evidence of unexpected, advantageous properties supported by the comparative test discussed above. *In re Kollman*, 595 F. 2d 48, 201 USPQ 193 (CCPA 1979). In *Kollman*, the submission of evidence showing the unexpectedly advantageous properties of the claimed combination supported a decision in favor of patentability, despite the disclosure in the prior art of the separate components and some general suggestions that one skilled in the art could consider combining the components together.

Reconsideration and withdrawal of the outstanding rejection is respectfully requested.

In view of the foregoing, Applicant believes the pending application is in condition for allowance. A Notice of Allowance is earnestly solicited.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By \_\_\_\_\_

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